UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,026	12/21/2001	Joseph J. Florio	99P1043US01	2420

7590 08/21/2003

PACESETTER, INC.
15900 Valley View Court
Sylmar, CA 91392-9221

EXAMINER
OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 08/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,026	FLORIO ET AL.	
	Examiner	Art Unit	
	Frances P. Oropeza	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2003 (Amendment)* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-18,20,22-30,32,34,36 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-18,20,22-30,32,34,36 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. The Applicant's arguments filed 7/10/03 have been fully considered and are convincing. The rejections of record are withdrawn and a new grounds of rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 103

2. Claims 1, 3, 5-12, 15-18, 20, 22-30, 32, 34, 36 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Begemann et al. (US 5978709) in view of Lu et al. (US 5951593).

Begemann et al. disclose a pacemaker system with improved techniques for preventing and suppression atrial arrhythmias.

As to claims 1, 3, 17, 18, 20, 29, 30, 32 and 36, the instant device/ method of pacing is disclosed by the special pacing treatment feature, the AFP feature of Pace Conditioning, wherein intrinsic beat(s) (one or more, read as two) are sensed whereupon the higher conditioning pacing repeats (figure 1; col. 2 @ 49 – col. 3 @ 2; col. 8 @ 50-54). The trigger to higher conditioning pacing can be a single intrinsic beat (col. 8 @ 51), or for example 2-3 consecutive intrinsic beats (col. 8 @ 53) or any predetermined program of rate adjustment (col. 8 @ 57).

As to claims 6, 10, 23, 27 and 39, the predetermined period is 10 cycles when the increase pace rate is 20 ppm and the increase is limited to 2 ppm/ cycle (col. 8 @ 20-32).

As to claims 5, 22 and 34, when the lower rate limit is reached a pace is provided and the conditioning pacing repeats (col. 6 @ 27-30).

As to claim 7, 8, 24, and 25, the special pacing treatment feature, the PAC suppression routine, decreases the overdrive pacing rate according to programmed criteria, this criteria reflecting any predetermined program of rate adjustment (col. 3 @ 3-14; col. 6 @ 32-65; col. 8 @ 56-60).

As to claims 11 and 28, the rate is decreased 1-3 ppm per 24-40 beats, read as about 1 to about 5 paces per minute (col. 9 @ 15-17).

As to claims 12 and 15, the underlying intrinsic rate is the atrial rate or the sinus rate (col. 5 @ 3-5).

As to claim 16, the selected pacing rate is reset to be the updated atrial rate (col. 7 @ 24-50).

As to claims 35 and 40, the predefined period is a predefined period of time (col. 9 @ 11-14).

Begemann et al. disclose the claimed invention except for increasing the pacing if at least two intrinsic beats are detected within the period of about 8 cycles and about 40 cycles (claims 1, 17, 18, 30 and 36), and the decrement of pacing beginning if two intrinsic heart beats are not detected within the second predefined period of about 8 cycles and about 40 cycles (claims 7, 9, 24 and 26).

As to increasing the pacing rate, Lu et al. teach cardiac rhythm monitoring using a known predetermined program of rate adjustment, dual counters, to determine the frequency of atrial sense signals for the purpose of controlling the pacing algorithm. When three signals over a period of eight cycles, read as two or more intrinsic signals over a period of eight cycles, are detected, an output is generated to control the pacing algorithm to prevent the onset of

arrhythmias. It would have been obvious to one having ordinary skill in the art at the time of the invention to have counted two or more intrinsic beats out of eight cycles to initiate incrementing the pacing rate in the Begemann et al. system in order to have a proven means to monitor the pacing rhythm and increasing the pacing rate, such that the onset of arrhythmias is prevented (col. 1 @ 6-12; col. 6 @ 50-63).

As to decreasing the pacing rate, Lu et al. teach cardiac rhythm monitoring using a known predetermined program of rate adjustment, dual counters, to determine the frequency of atrial sense signals for the purpose of controlling the pacing algorithm. When three signals over a period of eight cycles, read as two or more intrinsic signals over a period of eight cycles are detected, an output is generated to control the pacing algorithm. It would have been obvious to one having ordinary skill in the art at the time of the invention to have counted to two or more intrinsic beats out of eight cycle to initiate decrementing of the pacing rate in the Begemann et al. system in order to have a proven means to monitor the pacing rhythm and decreasing the pacing rate, such that the pacemaker responds to imminent atrial fibrillation and then after a predetermined period is reverted to normal operation, minimizing the unnecessary energy drain on the power source (col. 2 @ 11-24; col. 6 @ 50-63).

3. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Begemenn et al. (US 5978709) in view of Lu et al. (US 5951593 and further in view of Elmvist (US 5253644). As discussed in paragraph 2 of this action, modified Begemann et al. disclose the claimed invention of determining the pacing rate by suspending the pacing (figure 1 – 31, 32; col. 4 @ 50- col 5 @ 13) except for determining the sinus rate based on three consecutive sinus P-waves.

Elmvist teaches rhythm detection using at least two consecutive P-waves, read as three consecutive P-waves, for the purpose of accurately determining cardiac rhythm. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used three consecutive P-waves to calculate the sinus rate in the Begemann et al. system in order to use a proven method of rhythm determination and avoid inaccurate evaluation of the cardiac rhythm resulting in delayed treatment of the arrhythmia (abstract; col. 2 @ 26-29).

Statutory Basis

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
8/19/03

Angela D. Sykes

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700